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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/630,098	07/29/2003	Roger John Hill	03-001 (ANSI01-00013)	8483
37372	7590	09/23/2005	EXAMINER	
FULBRIGHT & JAWORSKI, L.L.P. (ANS) 2200 ROSS AVENUE SUITE 2800 DALLAS, TX 75201			KAHELIN, MICHAEL WILLIAM	
			ART UNIT	PAPER NUMBER
			3762	

DATE MAILED: 09/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.		Applicant(s)	
	10/630,098		HILL, ROGER JOHN	
	Examiner		Art Unit	
	Michael Kahelin		3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 September 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) 15-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 and 22-26 is/are rejected.
- 7) ☒ Claim(s) 12 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 December 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>12292003</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I, claims 1-14 and 22-26 in the reply filed on 9/2/2005 is acknowledged. The traversal is on the ground(s) that the two inventions are related as process and related apparatus and that the search for Group I could not be completed without the search for Group II. This is not found persuasive because the two groups are not related as process and related apparatus. Distinctness is shown, and restriction proper, if the apparatus could be used to perform another materially different process, or the process could be performed to manufacture another materially different apparatus. In the present case, the process could be performed to manufacture a lead with a conductor that is not electrically coupled to the connector and electrode. Furthermore, as specified in the previous Office Action, the two inventions are classified in different classes, creating a burden on the Examiner to complete the search. Invention I is limited to application to the body whereas Invention II does not include this limitation.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 15-21 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 9/2/2005.

Information Disclosure Statement

3. The information disclosure statement (IDS) submitted on 1/29/2003 is noted. The submission is in compliance with the provisions of 37 CFR 1.97 and 1.98. Accordingly, the information disclosure statement is being considered by the examiner.

Drawings

4. The drawings are objected to because elements 102 and 104 should be labeled 100 and 102 in Figure 3. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

5. Claim 12 is objected to because of the following informalities: "and expansion section" should read "an expansion section". Appropriate correction is required.
6. Claim 20 is objected to because of the following informalities: the claim is dependent on claim 1 and should depend on claim 15. Appropriate correction is required.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
8. Claims 2-4, 7 and 9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
9. In regards to claims 2 and 9, the claims are dependent on themselves, making the limitations of these claims unclear. Examiner is treating this as a typographical error and assuming that the claims depend from the claims directly preceding them.
10. In regards to claim 2, the claim is a product-by-process claim. This makes the claim vague because it is unclear whether Applicant is claiming a process or apparatus.
11. In regards to claim 7, it is unclear to what the conductor is conformal. Although the claim states that the conductor is "conformal within the expansion ring", it is unclear whether the conductor is conformal to the expansion ring.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claims 1 and 5-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Giele et al. (5,238,007).

14. In regards to claims 1 and 11, Giele et al. disclose a lead body having an expansion section (37), a connector (50), an electrode (32), and a conductor connecting the two (33).

15. In regards to claims 5 and 13, the lead body comprises a plurality of expansion sections (Fig. 1C and col. 4, line 41) and two expansion sections are spaced less than one inch apart (col. 4, line 15). Please note that, since the outside diameter of the lead is 1.7mm, it is inherent that the spacing between expansion sections is less than one inch.

16. In regards to claim 6, the expansion section (37) forms an expansion ring around the lead body (Fig. 1C).

17. In regards to claim 7, at least one conductor (33) is conformal within the expansion ring. It is conformal to the proximal electrode pin (34).

18. In regards to claims 8 and 14, the expansion section (37) allows expansion in the longitudinal direction (Figs. 1A and 1B).

19. In regards to claim 9, the expansion section provides increased elasticity of the lead body (col. 4, line 45). Giele et al. disclose that the combined contributions of elements 37 and 33 for keeping the lead in its steady state shown in Fig. 1A. Therefore, the expansion section (37) provides elasticity in the extension of the lead body.

20. In regards to claim 10, the expansion section is bubble-shaped (37, Fig. 1B).

21. In regards to claim 12, the expansion section (37) has a diameter greater than an adjacent section (36).

Claim Rejections - 35 USC § 103

22. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

23. Claims 2-4 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Giele et al.

24. In regards to claims 2 and 3, Giele et al. disclose an expansion section made of a polymer, such as silicone rubber (col. 3, line 56) that is preformed (col. 4, line 47). As such, it is inherent that the polymer material is heated on the lead body prior to forming the expansion section. In addition, the "formed by heating" adds no additional structural limitation and therefore Giele et al.'s invention meets the claim limitation of an expansion section. Or in the alternative, it is well known in the art to heat polymers to relieve the internal stresses, creating a resilient, preformed shape. Therefore, it would

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have been obvious to one having ordinary skill in the art at the time the invention was made to heat the expansion section prior to forming to relieve the internal stresses of the polymer, creating a resilient, preformed shape.

25. In regards to claim 4, Giele et al. disclose that the diameter of the expansion section (37) has a diameter that is at least about twice as great as the adjacent portion (36). This is shown by the geometric proportions disclosed in Fig. 1A. Alternatively, it would have been an obvious matter of design choice to one having ordinary skill in the art at the time of invention to modify the lead as taught by Giele et al. with the expansion section that has twice the diameter of the adjacent section because Applicant has not disclosed that an expansion section with twice the diameter provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the expansion sections as taught by Giele et al. because it provides a means for adequate expansion to connect the lead to the heart.

26. Claims 22-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Giele et al. in view of Levine et al. (6,081,747). Giele et al. disclose the essential features of the claimed invention except for a source that generates a stimulus comprising an RF receiver and a pulse generator and a controller that communicates with the source. Levine et al. disclose a device comprising a lead system (16), a source that generates stimulus pulses (79 and 80) for applying electrical therapy to the heart, an RF receiver (104 and col. 11, line 26) for communicating with an external device, and a controller that communicates with the source (108) to customize the parameters of the

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applied therapy. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Giele et al.'s invention by providing a source that generates stimulus pulses to apply electrical therapy to the heart, an RF receiver to communicate with an external device, and a controller that communicates with the source to customize the parameters of the applied therapy.

Conclusion

27. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Other examples of leads with expansion sections are provided.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Kahelin whose telephone number is (571)272-8688. The examiner can normally be reached on M-F, 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571)272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MWK

GEORGE R. EVANISKO
PRIMARY EXAMINER

9/2/5